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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,650	05/08/2001	Philip J. Barr	300622001610	4395

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EXAMINER

KERR, KATHLEEN M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 09/23/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/851,650

Applicant(s)

BARR ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 July 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Application Status***

1. Claims 1-39 are pending in the instant application.

### ***Restriction***

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 1-6, 8-14, 16, and 30-39, drawn to host cells, vectors, and methods of making polyketide synthases (PKSs), classified in class 435, subclass 183.
  - II. Claims 7, 15, 17, 25-26 drawn to methods of making polyketides and polyketide libraries, classified in class 435, subclass 252.3.
  - III. Claims 18-24, drawn to polyketide synthase (PKS) libraries, classified in class 435, subclass 183.
  - IV. Claims 18-24, drawn to polyketide libraries, classified in class 568, subclass 382.
  - V. Claims 27-29, drawn to methods of identifying polyketides which bind target receptors, classified in class 435, subclass 7.1.

Applicants' attention is drawn to claims 18-24 which are grouped in Groups III and IV. These claims must be separated into libraries of polyketide synthases (the enzymes) and libraries of polyketides (the products of the enzyme reaction). If Group III is elected, claims 18-24 will be examined as they pertain to libraries of polyketides. If Group IV is elected, claims 18-24 will be examined as they pertain to libraries of polyketide synthases. Appropriate cancellation of terms in claim 18 of the non-elected library is required in response to this Office action if either Groups III or IV are elected.

3. The inventions are distinct, each from the other, because of the following reasons:

Group I, drawn to host cells, vectors, and methods of making polyketide synthases (PKSs), and Group II, drawn to methods of making polyketides and libraries of polyketides, are related by virtue of PKSs which are made by the methods of Group I and which can make polyketides of Group II. However, these methods produce wholly different products, namely PKSs and polyketides, with different chemical compositions and different functions. Therefore, Groups I and II are patentably distinct.

The DNA of Group I is related to the enzymes of Group III by virtue of the fact that the DNA can encode the enzymes. The DNA molecule has utility for the recombinant production of the enzymes in a host cell. Although the DNA and the enzymes are related, they are distinct inventions because the enzyme product can be made by other and materially distinct processes, such as purification from a natural source. Furthermore, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays. Therefore, Groups I and III are patentably distinct.

Group I, drawn to host cells, vectors, and methods of making polyketide synthases (PKSs), and Group IV, drawn to polyketide libraries, are related by virtue of the polyketide synthases (PKSs) which are made by the methods and products of Group I and which produce the polyketides of Group IV. However, the methods of making PKSs in Group I do not directly produce polyketides in Group IV, and while the host cells and vectors in Group I produce and encode enzymes which produce polyketides, cells and vectors are different products from polyketides with wholly different chemical compositions and different functions.

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Group I, drawn to host cells, vectors, and methods of making polyketide synthases (PKSs), and Group V, drawn to methods of identifying polyketides which bind target receptors, are related by virtue of the polyketides which are produced by the products of the methods of Group I and which identified in Group V as binding to target receptors. However, the methods involve wholly different steps and reagents and produce different products as demonstrated by their different classifications. Therefore, Groups I and V are patentably distinct.

Group II, drawn to methods of making polyketides and polyketide libraries, and Group III, drawn to polyketide synthase (PKS) libraries are related since the PKS libraries are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the method of making polyketides and polyketide libraries can be practiced without using PKS libraries by using organic synthetic methods. Therefore, Groups II and III are patentably distinct.

Group II, drawn to methods of making polyketides and polyketide libraries, and Group IV, drawn to polyketide libraries, are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case, the polyketide libraries can be made by another materially different process such as by organic synthetic methods. Therefore, Groups II and IV are patentably distinct.

Group II, drawn to methods of making polyketides and polyketide libraries, and Group V, drawn to methods of identifying polyketides which bind target receptors, are related by virtue of the polyketides which are made by the methods of Group II and which are used in the methods of Group V. However, the methods involve wholly different steps and reagents and produce different products as demonstrated by their different classifications. Therefore, Groups II and V are patentably distinct.

Group III, drawn to polyketide synthase (PKS) libraries, and Group IV, drawn to polyketide libraries, are related since PKSs produce polyketides. However, PKSs (enzymes) are different products from polyketides with wholly different chemical compositions and different functions; enzymes function to catalyze reactions and polyketides are chemical compounds typically used as therapeutics. Therefore, Groups III and IV are patentably distinct.

Group III, drawn to polyketide synthase (PKS) libraries, and Group V, drawn to methods of identifying polyketides which bind target receptors, are related by the polyketides which are produced by the PKS libraries and which are used in the methods of identifying polyketides. However, the PKS libraries are not directly a part of the methods of identifying polyketides since the polyketides, not the PKSs, bind with the receptors in the method. Therefore, Groups III and V are patentably distinct.

Group IV, drawn to polyketide libraries, and Group V, drawn to methods of identifying polyketides which bind target receptors, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

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product (M.P.E.P. § 806.05(h)). In the instant case, the method of identifying polyketides can be used with different products, such as organically synthesized polyketides. Furthermore, the polyketides can be used in other processes, such as randomized drug screening for efficacy in particular enzyme assays. Therefore, Groups IV and V are patentably distinct.

### ***Election***

2. A telephone call was made to Brenda Wallach on September 20, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143). Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

### ***Conclusion***

4. A complete response to the instant Office action must include an election of invention to be examined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK

September 20, 2002

